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| APPLICATION NO.                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/528,353                          | 01/03/2006  | Nobuyuki Yasuda      | 082368-003300US     | 5028             |
| 20350                               | 7590        | 12/27/2007           | EXAMINER            |                  |
| TOWNSEND AND TOWNSEND AND CREW, LLP |             |                      | RAE, CHARLESWORTH E |                  |
| TWO EMBARCADERO CENTER              |             |                      | ART UNIT            |                  |
| EIGHTH FLOOR                        |             |                      | PAPER NUMBER        |                  |
| SAN FRANCISCO, CA 94111-3834        |             |                      | 1614                |                  |
| MAIL DATE                           |             | DELIVERY MODE        |                     |                  |
| 12/27/2007                          |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| <b>Office Action Summary</b> | <b>Application No.</b>             | <b>Applicant(s)</b>     |  |
|------------------------------|------------------------------------|-------------------------|--|
|                              | 10/528,353                         | YASUDA ET AL.           |  |
|                              | <b>Examiner</b><br>Charleswort Rae | <b>Art Unit</b><br>1614 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 13 November 2007.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 5-16,24-26,29 and 33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 5-16,24-26,29 and 33 are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ . 5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

**DETAILED ACTION**

***Status of Claims***

Claims 5-16, 24-26, 29, and 33 are pending in this application and are the subject of the Office action.

***Restriction and Election Requirement***

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of invention which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single species to which the claims must be restricted.

- I. Claims 5-16, and 24-26, drawn to a pharmaceutical agent comprising a dipeptidyl peptidase IV inhibitor and a biguanide agent in combination. If this Group is elected, then the below Summarized Species Election requirement is also required.
- II. Claim 29, drawn to a method for preventing or treating a disease which is associated with active circulating GLP-1 and/or active circulating GLP-2. If this Group is elected, then the below Summarized Species Election is also required.
- III. Claim 33, drawn to a method of enhancing the effects of active circulating GLP-1 and/or active circulating GLP-2. If this Group is elected, then the below Summarized Species Election is also required.

Inventions I, II, and III as represented above relate to a general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they share the same or corresponding technical feature i.e. a combination of a dipeptidyl peptidase IV inhibitor and another antidiabetic agent. However, the common technical feature is known in the art in view of the teaching of Arch et al. (WO 01/97808 A1; see especially abstract and pages 6-10). Thus, the inventions lack unity in view of Arch et al.

For the above reasons, the restriction is proper as the inventions lack unity of invention under PCT 13.1.

Applicant is required to elect a single invention for examination purposes.

***Species Election regarding Groups I-III***

This application contains claims directed to more than one species of the generic inventions. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. For example, the generic inventions encompass a multiple different of chemical compounds of formula I, which would reasonably exhibit varying pharmacologic effects and side-effect profiles depending on their affinity for the dipeptidyl peptidase IV enzyme; multiple different biguanide compounds, and multiple different clinical conditions. Methods of treatment comprising compositions of these different compounds of formula I in combination with a biguanide agent would reasonably have different treatment effects when administered to an individual. Further, to the extent that the diseases encompassed by the instant invention represent different patient populations and different etiologies, methods of treating/preventing these different diseases with the compositions encompassed by the generic inventions would reasonably be expected to result in

different therapeutic outcomes. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single disclosed species for examination purposes from the below list:

- 1) a single completely chemically defined dipeptidyl peptidase IV inhibitor compound species, wherein R1, X Z1, Z2, and T are completely defined e.g. 7-(2-butynyl)-2-cyano-1-methyl-8-(piperazin-1-yl)-1,7-dihydropurin-6-one;
- 2) a single completely chemically defined biguanide e.g. metformin; and
- 3) a single disease which is associated with active circulating GLP-1 and/or active circulating GLP-2 e.g. diabetes (see specification, pages 20, lines 15-19).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to the additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species (MPEP 809.02(a)). Claims 1, 29, and 33 are considered generic to the above species.

***Inventorship Notice***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

**may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 December 2007  
CER

BRIAN-YONG S. KWON  
PRIMARY EXAMINER

